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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,971	08/19/2003	Hans-Peter Berlien	08340.105016	7573
20786	7590	09/08/2006	EXAMINER	
KING & SPALDING LLP 1180 PEACHTREE STREET ATLANTA, GA 30309			BEISNER, WILLIAM H	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 09/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/644,971

Applicant(s)

BERLIEN ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/26/06</u> .   | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Priority***

1. Applicant is reminded that in order for a patent issuing on the instant application to obtain the benefit of priority based on priority papers filed in parent Application No. PCT/DE02/00581 under 35 U.S.C. 119(a)-(d) or (f), a claim for such foreign priority must be timely made in this application. To satisfy the requirement of 37 CFR 1.55(a)(2) for a certified copy of the foreign application, applicant may simply identify the application containing the certified copy.

### ***Information Disclosure Statement***

2. The information disclosure statement filed 6/26/06 has been considered and made of record.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Chou et al.(US 6,039,565).

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With respect to claim 1, the reference of Chou et al. discloses a device (60) that is structurally the same as that instantly claimed. Specifically, the reference discloses that the device (60) includes an ultrasonic transducer (64) and a glass fiber (62) coupled to the transducer (64). Note the glass fiber (64) is capable of transmitting ultrasonic energy into a vicinity of cells held within an inoculation medium.

With respect to claim 3, the glass fiber (62) is considered to be flexible since it is an extension of flexible fiber (26). The device also includes lumen or catheter (66).

5. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Tachibana et al. (WO 99/13943).

With respect to claim 1, the reference of Tachibana et al. discloses a device (10) that is structurally the same as that instantly claimed. Specifically, the reference discloses that the device (10) includes an ultrasonic transducer (20) and a glass fiber (See page 24, lines 15-20) coupled to the transducer (20). Note the glass fiber is capable of transmitting ultrasonic energy into a vicinity of cells held within an inoculation medium.

With respect to claims 2, 4, 6 and 8, the reference discloses the use of temperature sensors (22) for determining the ultrasonic energy produced by the transducer (See page 37, lines 4-30).

With respect to claim 3, the device includes a catheter (10) which is flexible. As a result, the glass fiber must also be flexible.

With respect to claims 5 and 7, the device is used to transmit ultrasonic energy via the catheter and glass fiber into a vicinity of cells to be inoculated in a fluid containing an

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inoculation medium and/or in a tissue aggregation (See page 12, lines 6-21; and page 18, lines 15-31).

6. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Langdon (US 4,240,285).

With respect to claim 1, the reference of Langdon discloses a device that is structurally the same as that instantly claimed. Specifically, the reference discloses that the device (See Figure 1) includes an ultrasonic transducer (5) and a glass fiber (2) coupled to the transducer (5). Note the glass fiber is capable of transmitting ultrasonic energy into a vicinity of cells held within an inoculation medium.

With respect to claim 2, the device includes measuring device (6) capable of determining when cavitation conditions exist.

7. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by McSkimin (US 2,707,391).

With respect to claim 1, the reference of McSkimin discloses a device that is structurally the same as that instantly claimed. Specifically, the reference discloses that the device (See Figure 1) includes an ultrasonic transducer (1) and a glass fiber ((4); see column 4, lines 23-25) coupled to the transducer (1). Note the glass fiber is capable of transmitting ultrasonic energy into a vicinity of cells held within an inoculation medium.

With respect to claim 2, the device includes measuring device (see Figure 2) capable of determining when cavitation conditions exist.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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11. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Jorsboe (WO 91/00358) or McKay (WO 89/02464) in view of either Langdon (US 4,240,285) or McSkimin (US 2,707,391).

Both of the references of Jorsboe and McKay disclose methods for effecting ultrasound-assisted inoculation of cells that includes providing a device comprising an ultrasonic transducer and a thin rod coupled to the ultrasonic transducer and transmitting ultrasonic energy via the thin rod into a vicinity of cells to be inoculated in a fluid containing inoculation medium (See page 7 of Jorsboe and page 5 of McKay).

While both references disclose the use of a thin rod, neither of the references discloses the use of a glass fiber.

Both the references of Langdon and McSkimin disclose devices for ultrasonically treating a liquid held within a vessel that includes a glass rod coupled to the ultrasonic transducer (See rod (2) of Langdon and rod (4) of McSkimin).

In view of either of these teachings, it would have been obvious to one of ordinary skill in the art employ a sonicating device disclosed by either of the secondary references to perform the method of the primary reference for the known and expected result of providing an alternative means recognized means for providing the required ultrasonic energy to the medium of cells.


### *Conclusion*

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
William H. Beisner  
Primary Examiner  
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WHB